II. REMARKS

A. Introduction

Applicants submit this Response in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully requests reexamination and reconsideration of the above referenced patent application in view of this Response.

As indicated above, Applicants have amended the specification and added new Figure 8 to further clarify the disclosed applied power of impact (or impact energy) and duration thereof. Applicants respectfully submit that the noted amendments and added figure merely make explicit that which was (and is) disclosed or implicit in the original disclosure. The amendments and new figure thus add nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

B. Response to Rejections

Claim 8 is rejected under 35 USC § 103(a) as being unpatentable over Theeuwes et al. (WO 98/28037). Theeuwes et al. discloses a method of delivering or sampling glucose through the stratum corneum with a microprotrusion member, forming microslits and delivering or sampling glucose through the microslits. The Examiner admits that the Theeuwes reference does not disclose impacting the stratum corneum with a power of at least 0.05 joules per cm^2 in 10 milliseconds or less. However, the Examiner has concluded that "it would have been an obvious matter of design choice to a person of ordinary skill in the art to impact the stratum corneum with a power of at least 0.05 joules per cm2 of the microprotrusion member in 10 milliseconds or less because Applicants has not disclosed that this measurement provides an advantage, is used for a particular purpose, or solves a stated problem." Applicants respectfully request that the Examiner reconsider this conclusion for the following reasons:

First, Applicants submit that the specification, as filed, does indeed disclose benefits associated with applying the microprotrusion member by impacting it with the specific claimed energy. On page 5, in paragraph 13, the specification teaches that the applicator device delivers sufficient power for effective penetration of the stratum corneum. The specification next states that "impact spring 20 is also preferably selected to achieve the desired skin penetration without

exceeding an impact which causes discomfort to the patient" on page 9, in paragraph 29. Then, the specification states that "impact spring 20 is preferably selected to deliver a minimum amount of energy of 0.05 Joules per cm^2, which is delivered in less than 10 milliseconds (msec)." Therefore, the specification clearly teaches that using the claimed impact energy results in the benefit of creating uniform, effective penetration of the stratum corneum.

This teaching is reinforced by Examples 1 and 2, page 12-14, paragraphs 41-44, which compare the use of an impact applicator that utilizes the claimed amount of energy in the specified time to manual application. These examples demonstrate that impact application of the microprotrusion member with the claimed power parameters results in an increased rate of agent delivery. Applicants submit that this is also clearly a benefit.

Second, the specification discloses that applying the microprojection member in the claimed manner solves a specific problem, inconsistent application, because impact application using the claimed energy parameters achieves the particular purpose of creating effective, uniform penetration of the stratum corneum. For example, on pages 2-3, paragraph 6, the specification states that it is desirable to effect "consistent, complete and repeatable penetration of the skin." However, prior art means of applying a microprotrusion member result in "significant variation in puncture depth across the microprotrusion array" and in "large variations in puncture depth between applications." The present invention solves these problems by causing "the microprotrusion member to impact the stratum corneum with a certain amount of impact determined to effectively pierce the skin with the microprotrusions." (Page 3, Para. 8).

In contrast, as the Examiner admits, the Theeuwes reference does not disclose or suggest the use of the claimed impact parameters. Indeed, Theeuwes et al. does not disclose any specific means of applying the microprojection member. Thus, Applicants respectfully submits that Theeuwes et al. provides no teaching that would allow one having skill in the art to deliver a microprojection member with the claimed energy in the specified time.

Also, the results of the noted experiments contradict the Examiner's conclusion that "one of ordinary skill in the art, furthermore, would have expected Applicants's invention to perform equally well with either the measurement taught by Theeuwes or the claimed measurement." As admitted by the Examiner, Theeuwes et al. does not recite any delivery parameters and makes no suggestion of the type of impact delivery claimed in this invention. Thus, the Theeuwes reference provides no specific "measurements" at all. However, the experiments show that a

microprotrusion member applied with the claimed impact energy provides enhanced transdermal delivery as compared to the manual application of a microprotrusion member inherently taught by Theeuwes et al.

For the above reasons, Applicants request that the Examiner withdraw the § 103(a) rejection of Claim 8 over Theeuwes et al.

Next, the Examiner rejected Claims 1-3, 7, 10 and 11 under 35 USC § 103(a) as being unpatentable over Theeuwes et al. (WO 98/28037), Effenhauser (WO 96/17648), Gerstel et al. (US 3,964,482), Gross et al. (US 5,279,544) and Godshall et al. (US 5,879,326). The Examiner states that each of these references discloses a method of delivering or sampling glucose through the stratum corneum with a microprotrusion member, forming microslits and delivering or sampling glucose through the microslits. The Examiner concedes that the cited references do not disclose impacting the stratum corneum with a power of at least 0.05 joules per cm^2 in 10 milliseconds or less. However, the Examiner has concluded that "it would have been an obvious matter of design choice to a person of ordinary skill in the art to impact the stratum corneum with a power of at least 0.05 joules per cm2 of the microprotrusion member in 10 milliseconds or less because Applicants have not disclosed that this measurement provides an advantage, is used for a particular purpose, or solves a stated problem."

This is the same reasoning that was applied with respect to the rejection of Claim 8, and the Examiner has not indicated that the additional references provide any teaching that goes beyond the teaching of Theeuwes et al. discussed above. Accordingly, Applicants respectfully submit that rejection of these claims is improper for the same reasons that Claim 8.

As discussed above, Applicants submit that the specification as filed does provide a clear teaching that the claimed impact delivery parameters yield a specific advantage, achieve a particular purpose and solve a stated problem. Namely, the claimed impact energy uniformly and effectively causes the microprotrusions to penetrate the stratum corneum. This solves the problems of variable penetration of the microprotrusions and inconsistent application. As noted in Examples 1 and 2, the uniform and reproducible penetration afforded by the use of the claimed impact energy provides improved transdermal delivery as compared to the manual application of the prior art.

The Examiner also reiterated that one of skill would have expected equal performance with either the measurement taught by the cited references or the claimed measurement.

However, in the examples discussed above, a microprotrusion member applied with the claimed impact energy clearly provides improved delivery over the manually applied microprotrusion member inherently taught by the cited references. Thus, Applicants' invention represents a significant advantage over the delivery taught by the Examiner's cited art.

Moreover, the additional references cited by the Examiner suffer from the same deficiencies discussed above regarding Theeuwes et al. alone. Namely, none of the prior art cited by the Examiner suggests applying a microprotrusion member by impacting the member with specific energy. Additionally, the Examiner has failed to indicate any teaching in the prior art that would allow one having skill in the art to deliver a microprotrusion member with the claimed energy parameters in the specified time or any suggestion that such delivery is desirable.

In summary, Applicants teach that using the claimed energy parameters to impact the stratum corneum with a microprotrusion member provides uniform and effective penetration of the skin that improves transdermal delivery. The references cited by the Examiner offer no teaching regarding the use of the claimed parameters and thus do not suggest the invention.

For these reasons, Applicants request that the Examiner withdraw the § 103(a) rejection of Claims 1-3, 7, 10 and 11 under 35 USC § 103(a) over Theeuwes et al., Effenhauser, Gerstel et al., Gross et al. and Godshall et al.

III. CONCLUSION

For the above reasons, Applicants submit that the pending claims are patentable over the art of record. To expedite prosecution of the case, the Examiner is invited to contact the undersigned at the telephone number below to discuss any aspect of the application.

Respectfully submitted,
Francis Law Group

By _____
Ralph C. Francis
Reg. No. 38,884

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FRANCIS LAW GROUP
1808 Santa Clara Avenue
Alameda, CA 94501
(510) 769-9800